

EXPRESS MAIL CERTIFICATE

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Deposit Date JUNE 2, 1994

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington DC 20231

126 *Mr. Ronald C. Fedus* **RECEIVED** JUNE 2, 1994

Ronald C. Fedus Date

- ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
- ☐ A check in the amount of \$200.00 is enclosed in payment of the fee.
- ☒ Charge the fee to Deposit Account No. 05-1135, Order No. ENZ-7 (C2)(P)(C2). A DUPLICATE COPY OF THIS SHEET IS ATTACHED.
7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- ☐ one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
 - ☐ the attached petition requesting consideration of this Information Disclosure Statement; and
 - ☐ the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
 - ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issu .

Jannis G. Stavrianopoulos et al.
Serial No.: 07/967,646
Filed: October 28, 1992
Pag 3 (Information Disclosure Statement
Under 37 C.F.R. §§1.56 & 1.99 - June 2, 1994)

c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

10. ☐ A check in the amount of \$130.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

☐ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. _____. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: JUNE 2, 1994

By: 
RONALD C. FEDUS

Registration No. 32,567

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Enz-7 (C2)(P)(C2)

1507

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jannis G. Stavrianopoulos et al.

Serial No. 07/967,646

Filed: October 28, 1992

Title: COMPOSITION AND KIT EMPLOYING
CHEMICALLY LABELLED POLYNUCLEOTIDE
PROBES (As Amended)

Group Art Unit: 1807

Examiner: Ardian Mersha
Ph.D.

RECEIVED
JUN 16 1994
GROUP 1800

575 Fifth Avenue, 18th Floor
New York, New York 10017
June 2, 1994

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Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

**INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. §§1.56 & 1.99**

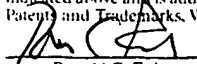
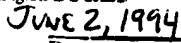
Dear Sirs:

This Information Disclosure Statement follows the April 22, 1994 filing of Applicants' Amendment Under 37 C.F.R. §1.115. On page 6 of that Amendment, Applicants' undersigned attorney indicated that art-related documents were being assembled for inclusion in an Information Disclosure Statement.

Applicants have now completed retrieval and assembly of the documents in question. Accordingly, pursuant to the provisions of 37 C.F.R. §1.99 and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following forty-seven (47) documents (Exhibits 1-47) to the attention of the U.S. Patent and Trademark Office and the Examiner:

1. Falkow et al., U.S. Patent 4,358,535, issued November 9, 1992^{1, 13, 15}
{Exhibit 1};

Enz-7 (C2)(P)(C2)

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 Ronald C. Fedus	 Date JUNE 2, 1994

2. Langer et al., "Enzymatic Synthesis of Biotin-Labeled Polynucleotides: Novel Nucleic Acid Affinity Probes," Proc. Natl. Acad. Sci. (USA) 78(11):6633-6637 (Nov. 1981)^{1, 2, 8, 13} {Exhibit 2};
3. Ward et al., U.S. Patent No. 4,711,955, issued December 8, 1987 (based upon priority document U.S. Patent Application Serial No. 06/255,223)¹ {Exhibit 3};
4. Ruth et al., "C-5 Substituted Pyrimidine Nucleosides. 1. Synthesis of C-5 Allyl, Propyl, and Propenyl Uracil and Cytosine Nucleosides via Organopalladium Intermediates," J. Org. Chem. 43(14):2870-2876 (1978)¹ {Exhibit 4};
5. Bergstrom et al., "C-5 Substituted Pyrimidine Nucleosides. 2. Synthesis, via Olefin Coupling to Organopalladium Intermediates Derived from Uridine and 2'-Deoxyuridine," J. Amer. Chem. Soc. 100(26):8106-8112 (1978)¹ {Exhibit 5}
6. Bigge et al., "Palladium-Catalyzed Coupling Reactions of Uracil Nucleosides and Nucleotides," J. Amer. Chem. Soc. 102:2033 (1980)¹ {Exhibit 6};
7. Engelhardt et al., U.S. Patent No. 5,241,060, issued August 31, 1993 (based upon priority document U.S. Patent Application Serial No. 06/391,440)¹ {Exhibit 7};
8. Miller, U.S. Patent 3,669,841, issued June 13, 1972¹ {Exhibit 8};
9. Miller, U.S. Patent 3,715,278, issued February 6, 1973¹ {Exhibit 9};
10. Bornstein et al., U.S. Patent 3,949,064, issued April 6, 1976¹ {Exhibit 10};
11. Barrett, U.S. Patent 4,001,583, issued January 4, 1977¹ {Exhibit 11};
12. Johnson, U.S. Patent 4,059,685, issued November 22, 1977^{1, 2} {Exhibit 12};

13. Gutcho et al., U.S. Patent 4,120,945, issued October 17, 1978¹
{Exhibit 13};
14. Sugiura et al., U.S. Patent 4,280,992, issued July 28, 1981¹ {Exhibit 14};
15. Weetal et al., "Porous Glass for Affinity Chromatography Applications,"
Methods in Enzymology, Vol. 34, Affinity Techniques Enzyme Purification:
Part B, pp. 59-72 (Jakoby, W.B. and Wilchek, M., eds.) (1974)^{1, 2}
{Exhibit 15};
16. Filippusson et al., "The Preparation and Properties of Yeast β -
Fructofuranosidase," Biochem J. 120:215-219 (1970)^{1, 2} {Exhibit 16};
17. Chard T., An Introduction To Radioimmunoassay And Related Techniques,
Elsevier Science Publishers, B.V. (1978)^{3, 4, 12} {Exhibit 17};
18. Grunstein, M., "Colony Hybridization: A Method For The Isolation of Cloned
DNAs That Contain A Specific Gene," Proc. Natl. Acad. Sci. (USA) 72:3961-
3965 (1975)⁴ {Exhibit 18};
19. Kourilsky et al., U.K. Patent Application No. 2 019 408 A, published October
31, 1979^{2, 3, 14} {Exhibit 19};
20. Stavrianopoulos et al., "Glycosylated DNA Probes For Hybridization/
Detection of Homologous Sequences," presented at the Third Annual
Congress For Recombinant DNA Research (1983)⁴ {Exhibit 20};
21. Singer et al., "Actin Gene Expression Visualized In Chicken Muscle Tissue
Culture by Using In Situ Hybridization With A Biotinated Nucleotide Analog,"
Proc. Nat'l Acad. Sci (USA) 79:7331-7335 (1982)^{4, 14} {Exhibit 21};
22. Ward et al., European Patent No. 0 063 879 B1, granted November 23,
1989 (based upon priority document U.S. Patent Application Serial No.
06/255,223)^{2, 3, 10, 14} {Exhibit 22};

23. David et al., U.S. Patent No. 4,376,100, issued March 8, 1983⁴
{Exhibit 23};
24. Heller et al., European Patent Application Publication No. 0 070 685,
published January 26, 1983⁴ {Exhibit 24};
25. Heller et al., European Patent Application Publication No. 0 070 687,
published January 26, 1983^{4, 14} {Exhibit 25};
26. Mattiasson et al., U.S. Patent No. 4,312,944 issued January 26, 1982³
{Exhibit 26};
27. Kennell, "Principles and Practices of Nucleic Acid Hybridization," Progr. Nuc.
Acid. Res. Mol. Biol., Vol. 11, pp. 259-262 (1971)³ {Exhibit 27};
28. Kourilsky et al., U.S. Patent No. 4,581,333, issued April 8, 1986⁵
{Exhibit 28};
29. Gillespie et al., U.S. Patent No. 4,483,920, issued November 20, 1984⁵
{Exhibit 29};
30. Litman et al., U.S. Patent No. 4,391,904, issued July 5, 1983⁶ {Exhibit 30};
31. Alberts et al., Molecular Biology of the Cell, Garland Publishers, New York
and London (1983), p. 719⁷ {Exhibit 31};
32. Hood et al., Immunology, Benjamin/Cummings Publishing Co., Inc. Menlo
Park, CA (1978), p. 142⁷ {Exhibit 32};
33. Stavrianopoulos et al., U.S. Patent No. 4,994,373, issued February 19,
1991^{8, 9} {Exhibit 33};
34. Ranki et al., U.S. Patent No. 4,563,419, issued January 7, 1986⁸
{Exhibit 34};

35. Engelhardt et al., European Patent No. 0 097 373 B1, granted October 7, 1992¹⁰ {Exhibit 35};
36. Kourilsky et al., WO 83/02277, published July 7, 1983¹⁰ {Exhibit 36};
37. Sugiura et al., GB-A-2,014,727, published August 30, 1979¹¹ {Exhibit 37};
38. Schuurs et al., "Enzyme Immunoassay," Clinica Chimica Acta 81:1-40 (1977) {Exhibit 38};
39. Langer et al., "Immunological method for mapping genes on Drosophila polytene chromosomes," Proc. Natl. Acad. Sci. (USA) 79:4381-4385 (July 1982) {Exhibit 39};
40. Leary et al., "Rapid and sensitive colorimetric method for visualizing biotin-labeled DNA probes hybridized to DNA or RNA immobilized on nitrocellulose:Bio-blots," Proc. Natl. Acad. Sci. (USA) 80:4045:4049 (July 1983) {Exhibit 40};
41. DE-A-29 15 082, published October 31, 1979¹³ {Exhibit 41};
42. DE-A-27 24 486, published December 22, 1977¹⁵ {Exhibit 42};
43. Bunting, U.S. Patent No. 4,271,140 issued June 2, 1981 {Exhibit 43};
44. Guesdon et al., "The Use of Avidin-Biotin Interaction in Immunoenzymatic Techniques," Journal of Histochemistry and Cytochemistry 27(8):1131-1139 (1979) {Exhibit 44};
45. Avrameas et al., "Enzyme-immunoassay for the measurement of antigens using peroxidase conjugates," Biochimie 54:837-842 (1972) {Exhibit 45};

46. Bauman et al., "A new method for fluorescence microscopical localization of specific DNA sequences by in situ hybridization of fluorochrome-labelled RNA," Exp. Cell Res. 128:485-490 (1980) {Exhibit 46};
47. Boguslaski et al., "Chemiluminescent-labeled conjugates for use in specific binding assays," GB-A-2,026,690, published February 6, 1980 {Exhibit 47};

Of the forty-seven (47) above-submitted documents, twenty-five (25) documents (Exhibits 1-25) were cited in the instant specification and/or in the specifications of predecessor applications (see footnotes to exhibits for further information), and nine (9) documents were made of record during the prosecution of predecessor applications (Exhibits 26-34). In addition, three (3) documents (Exhibits 35-37) were cited by the European Patent Office in search reports for the corresponding European applications, namely:

- a) European Patent Application No. 84100836.0, filed January 1, 1984 (granted as European Patent No. 0 117 400 B1 on April 7, 1993) (Exhibits 35-36); and
- b) European Patent Application No. 92114727.8, filed August 28, 1982 (Exhibit 37).

Finally, ten (10) documents (Exhibits 38-47) were cited by two separate parties in oppositions filed recently against European Patent No. 0 117 400 B1. Although the opposers' statements have not been submitted, copies will be provided to the Examiner upon request.

Completed Forms PTO-1449 (5 sheets) listing the above-submitted documents are also attached hereto as Exhibit 48.

The above citation of references is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant references, nor are these documents necessarily a complete listing of all references known to Applicants or their attorney. It is simply a voluntary citation of references made in good faith,

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Serial No.: 07/967,646
Fil d: October 28, 1992
Page 7 (Information Disclosure Statement
Under 37 C.F.R. §§1.56 & 1.99 - June 2, 1994)

which is not intended to serve in any way as a substitute for the Examiner's own search or search efforts.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither suggested nor disclosed by the documents referred to above and is thus patentably distinct thereover. Applicants do not believe, and do not submit, by the citation of these references, that these references, either by themselves or in combination with other references, render the invention *prima facie* obvious under the new duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$200.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus
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Attorney for Applicants

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Footnote Text to Exhibits 1-47

1. First cited in the specification of U.S. Patent Application Serial No. 06/461,469, filed January 27, 1983.

Enz-7 (C2)(P)(C2)

2. Also cited in the specifications of U.S. Patent Application Serial Nos.: 06/732,374 filed May 9, 1985; 07/385,986 filed July 20, 1989 (which issued on February 19, 1991 as U.S. Patent No. 4,994,373); and 07/607,347 filed October 30, 1990.
3. Cited in a November 9, 1987 Office Action issued in connection with U.S. Patent Application Serial No. 06/461,469.
4. First cited in the specification of U.S. Patent Application Serial No. 06/732,374, filed May 9, 1985.
5. Cited in a January 19, 1988 Office Action issued in connection with U.S. Patent Application Serial No. 06/732,374.
6. Cited in a January 4, 1990 Office Action issued in connection with U.S. Patent Application Serial No. 07/385,986, filed July 20, 1989, which application issued as U.S. Patent No. 4,994,373 on February 19, 1991.
7. Cited in a July 3, 1990 Response Under 37 CFR 1.115 in connection with U.S. Patent Application Serial No. 07/385,986, filed July 20, 1989, which application issued as U.S. Patent No. 4,994,373 on February 19, 1991.
8. Cited in a March 28, 1991 Office Action issued in connection with U.S. Patent Application Serial No. 07/607,347, filed October 30, 1990.
9. Cited in October 22, 1993 Office Action issued in connection with U.S. Patent Application Serial No. 07/967,646, filed October 28, 1992.
10. Cited by the European Patent Office (EPO) in the search report for European Patent Application No. 84100836.0, filed January 1, 1984, granted as European Patent No. 0 117 440 on April 7, 1993.
11. Cited by the EPO in the search report for European Patent Application No. 92114727.8, filed August 28, 1982, which application is a divisional of European Patent No. 0 117 440 B1.
12. The 1978 edition of this work was not available; submitted herewith is Chapter I, pp. 1-25 of the 1987 third revised edition of this work.
13. This German Patent was not available; an English abstract (DERWENT) of this patent is submitted herewith; the complete text of a U.S. patent from the family, Kourilsky et al., U.S. Patent No. 4,581,333, is submitted herewith as Exhibit 28.
14. Cited in either or both oppositions to European Patent No. 0 117 440 B1.
15. An English abstract (DERWENT) of this German patent is annexed to this exhibit. Additionally, Cais, U.S. Patent No. 4,205,952, a member of the family of patents cited in the abstract, is also annexed hereto.

* * * * *